

REMARKS

In the Office Action dated March 4, 2008, the Examiner sets forth a requirement for restriction under 35 U.S.C. §§121 and 372, alleging that the subject matter defined by the claims of the present invention represents the following four separate and distinct inventions:

- Group I. claim(s) 1-19 and 44-47, drawn to a genetically modified cell or non-human animal.
- Group II. claim(s) 20-27 and 31-43, drawn to a method for phenotyping a cell of the hematopoietic system.
- Group III. claim(s) 28, 29, and 31-43, drawn to a method for testing the antigenicity or immunogenicity of a vaccine.
- Group IV. claim(s) 30-43, drawn to a method of screening for agonists or antagonists of terminal differentiation of hematopoietic cells.

According to the Examiner, the identified groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, these groups lack the same or corresponding special technical features for the following reasons:

- A) The invention has no special technical feature that defined the contribution over the prior art, or
- B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present.

Referring to MPEP 1850, the Examiner states that the allowed combinations do not include multiple products, multiple methods of using said products, or methods of making multiple products, as claimed in the instant application. The Examiner contends that the instant claims are drawn to multiple methods of using the product. The Examiner further states that should the invention I be elected for prosecution, further species election is required as follows:

- A. Functional (claim 6) or non-functional Blimp (claim 7);
- B. B-cells (claim 14) or T-cells (claim 16).

The Examiner indicates that there is an examination and search burden for the patentably distinct species due to their mutually exclusive characteristics. Applicants are required to elect a single disclosed species from each group A and B for prosecution on the merits, to which the claims shall be restricted if no generic claim is finally held to be allowable.

In order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, Group I, Claims 1-19 and 44-47, drawn to a genetically modified cell or non-human animal. Applicants further elect "functional Blimp" and "B-cells" in response to the species election. Applicants further submit that within Group I, claims 1-5 and 44-47 are generic relative to the elected species, "functional Blimp", and claim 6 reads specifically on "functional Blimp". Further, claims 1-13, 15-19 and 44-47 are generic relative to the elected species, "B-cells", and claims 13-14 recite specifically "B-cells".

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention')." (Emphasis added.) PCT Rule 13.2 states: "The expression 'technical features' shall mean those technical features that define a contribution

which each of the claimed inventions, considered as a whole, makes over the prior art."

(Emphasis added.)

Applicants respectfully submit that Groups II-IV represent methods of using the product of Group I. Specifically, the method of phenotyping a cell of the hematopoietic system, i.e., the subject matter of Group II, is based on screening a genetically modified hematopoietic cell or a genetically modified animal (product of Group I) for activity of the reporter gene. The method for testing the antigenicity or immunogenicity of a vaccine, i.e., the subject matter of Group III, is based on administering the vaccine to a genetically modified hematopoietic cell or a genetically modified animal (product of Group I) and testing for the presence of the reporter molecule. The method of screening for agonists or antagonists of terminal differentiation of hematopoietic cells (Group IV) is based on exposing the candidate agent to a genetically modified hematopoietic cell or a genetically modified animal (Group I) and testing for the presence or change in the level of the reporter molecule. Therefore, Group I and Groups II-IV are related to each other as product and process of use, which falls within the allowed combination of claims. See Item 2) on page 3 of the Office Action.

Applicants respectfully submit that Groups I-IV are related to each other as different aspects of a single invention. Applicants further submit that the interdependence of Groups I-IV as different aspects of a single invention is confirmed --indeed, it is mandated-- by virtue of the fact that 35 U.S.C. §112 compels disclosure of all aspects of the invention in the one application which applicants have filed. In other words, a description of the means and method for using the genetically modified cell or non-human animal of Group I is a mandatory part of the application to the genetically modified cell or non-human animal itself. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first

paragraph.

With respect to the species restriction, Applicants wish to note that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 C.F.R. §1.141.

Finally, Applicants respectfully submit that a determination to make the pending group and species restriction requirement final must evidence the patentable distinctness of all defined groups and species, one from another, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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